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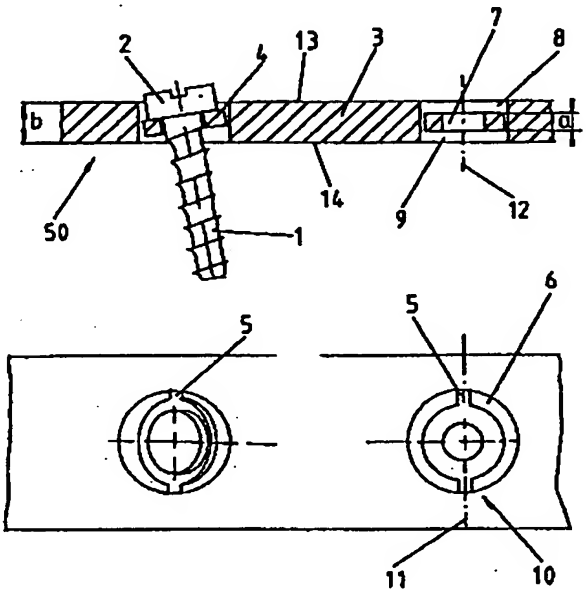
(54) IMPLANT OSTEOSYNTHETIQUE DOTE D'UN ASSEMBLAGE ARTICULE ENCASTRE

(54) OSTEOSYNTHETIC IMPLANT WITH AN EMBEDDED HINGE JOINT




(57) L'invention concerne un dispositif comprenant un implant ostéosynthétique ou un élément implant et au moins une articulation (10) reliée à l'implant ou à l'élément implant. Chaque articulation (10) comprend au moins un élément pivotant (4; 16) plat en forme de plaque ou d'anneau et, par élément pivotant (4; 16) deux moyens de liaison (5; 15) qui sont en forme de bâtonnet plat et placés dans un axe (11; 18; 36; 37) situé sur la périphérie extérieure de l'élément pivotant (4; 16). Ces axes constituent des axes de rotation. Un élément pivotant (4; 16) est relié pivotant à l'implant ou à l'élément implant à l'aide des moyens de liaison (5; 15). En fonction de son mode de réalisation, l'articulation (10) sert à recevoir un moyen de fixation osseuse (1; 19).

(57) The invention relates to a device comprising an osteosynthetic implant or implant part and at least a joint (10) connected to the implant or the implant part. Each joint (10) comprises at least one flat disc or annular pivoting element (4; 16) and each pivoting element (4; 16) includes two flat rod-shaped connecting elements (5; 15) placed on an axis located outside the outer periphery of the pivoting element (4; 16) and forming the axes of rotation. A pivoting element (4; 16) is pivotally connected to the implant or the implant part by means of a connecting element (5; 15). The joint (10) can be used to receive a bone fixing element (1; 19) depending on its embodiment.

1670/PCT
28.9.2000



**Englisch translation of the amendments as annexed to the International Preliminry Examination Report of the International Patent Application No. PCT/CH98/00208 in the name of Synthes AG Chur**

OSTEO-SYNTHETIC IMPLANT WITH PLANAR GIMBAL(S).

The invention relates to a device comprising an osteosynthetic implant or implant element and at least one swivel means linked to the implant or implant element, as defined in the preamble of claim 1.

Angularly fixed longitudinal supports such as plates and bars are increasingly used in osteosynthesis. Foremost they are advantageous in treating fractures near joints or when anchoring screws in the spinal column. When only short screws are being used, they may be inserted at a predetermined angle into the longitudinal support. If however significantly longer screws must be used, problems may arise with a system-constrained, predetermined screw direction. To circumvent such problems, special ball joints have been developed, for instance for the region of the spinal column. The state of the art discloses specially configured boreholes to receive correspondingly shaped screw heads and allowing locking the bone screw in the bone plate fairly independently of direction. A bone plate with such specially configured screw holes and matching screw heads is described in the German patent 195 48 395.

However neither ball joints nor screw heads with matching boreholes in the implant potions have been optimal in addressing the above problem of system-constrained, predetermined bone-screw directions. Either manufacture is unduly complex, or the affixation's loading strength is inadequate. Furthermore, depending on indication, these known designs also are too bulky.

In DE 24 38 669 BEZOLD an osteosynthetic plate having screw holes with a distance being variable through external application of a force is disclosed. The screw holes are provided within eyes that are cut out of the main body of the osteosynthetic plate and are solely connected to the osteosynthetic plate through resilient fins. In one embodiment of this known device the fins are connected with the eye in alignment with one axis and diametrical relative to this axis. Disadvantageous at this known device is

that upon swivelling the eye relative to the plane of the plate the fins are bended such that the swivelling axis is no longer identical to the axis of the eye and of the screw hole respectively. Thus, upon swivelling the eye the centre of the screw hole is displaced, what is negative in clinical applications.

The objective of the invention is palliation. Its purpose is to create a flat planar swivel means allowing to connect an implant element, for instance a bone screw, in either single or doubled gimbaled manner with a further implant element, for instance a bone plate.

The invention solves this problem by means of a device composed of an osteosynthetic implant or implant element and at least one swivel means connected to the implant or implant element and with the features of claim 1.

Further advantageous embodiments of the invention are defined in the dependent claims.

In a preferred embodiment of the device of the invention, the swivel means situated within an osteosynthetic implant comprises two planar, bar-shaped connecting arms located in one axis and opposite each other and affixed by their outer sides to the implant or implant element and by their inner sides to a planar or annular gimbal. The gimbal is mounted through the connecting arms so as to be pivotable about the axis of rotation formed by these arms and is affixed in a borehole of the implant or implant element.

Another embodiment of the device of the invention differs from the above embodiment only in that the implant or implant element and the articulation consisting of the connecting arms and the gimbal are integral.

Yet another embodiment of the device of the invention only differs from the above described embodiment in that the two planar, bar-shaped connection means are of dimensions such that due to plastic deformation they allow an angularly fixed position of the gimbal rotated relative to the implant or implant element.

Another embodiment of the invention differs only from the ones described above in that the connecting arms between the planar or annular gimbal and the implant or implant element are replaced by pivot shafts, and in that the gimbal is supported concentrically in a borehole of the implant or implant element and is rotatable about the pivot axes.

Yet another embodiment of the device of the invention only differs from the above ones in that the pivot element thickness is less than the thickness "b" of the implant or of the implant-wall receiving the swivel means.

Yet another embodiment of the device of the invention differs from the above ones only in that two gimbals are so nested into each other that the outer one is mounted in the borehole in the implant or implant element and in that a further, inner gimbal is rotatably supported within a borehole in the outer gimbal.

Yet another embodiment of the device of the invention differs from the above ones only in that the axes of rotation of the bar-shaped connections of two mutually nested gimbals are offset by 90ø.

Yet another embodiment of the device of the invention differs from the above embodiments only in that the gimbals are separated by slots from the implant or implant element as far as the connecting arms and in that these slots are annular.

Another embodiment of the device of the invention is characterized in that the swivel means is integrated into a bone plate.

Yet another embodiment of the device of the invention is characterized in that the swivel means is integrated into a receiving head to connect a pedicle screw to a longitudinal support inside a vertebral affixation system.

Yet another embodiment of the device of the invention is characterized in that one swivel means each is integrated into the top side and into the bottom side of vertebra.

The vertebral unit may be designed in another embodiment so that the element joining the two vertebral end plates is a bar connected at its two ends to the inner gimbals

and perpendicularly to the axes of rotation of the swivel means of the invention. The vertebral end plates adjoining the vertebras are oval rings and connected to the connecting arms of the outer gimbals. Accordingly the two vertebral end plates are connected to said bar each by an swivel means and each in rotatable manner about at least one axis of rotation.

Yet another embodiment of the device of the invention differs from the above embodiments in that the gimbal is fitted with a borehole to receive an bone affixation means, in particular a bone screw or a pedicle screw.

Yet another embodiment of the device of the invention differs from the above embodiment in that the gimbal borehole receiving a bone affixation means is conical and in that the bone affixation means or the bone screw or the pedicle screw is fitted with a screw head of corresponding conical shape and in that an angularly-fixed connection can be made between the implant or implant element and the bone affixation means.

A further embodiment of the device of the invention is characterized in that, relative to the above embodiment, the gimbal borehole is fitted with an inside thread and the bone affixation means or bone screw or pedicle screw is fitted at the screw head with a corresponding outer thread and that thereby an angularly fixed connection can be established between the implant or implant element and the bone affixation means.

Another embodiment of the device of the invention is characterized over the above described one in that the bone affixation means, ie the bone screw or the pedicle screw, is fitted with an expansible head and in that using a tightening screw the pieces of this expansible head are snugly pressed against the borehole wall and thereby an angularly fixed connection can be established between the implant or implant element and the bone affixation means.

Another embodiment of the device of the invention is characterized over the above described one in that the gimbal borehole is fitted with an conical inner thread and the bone affixation means, ie the bone screw or the pedicle screw, is fitted with a corresponding outer thread at the screw head and in that thereby an angularly fixed

connection can be established between the implant or implant element and the bone affixation means.

Yet another embodiment of the device of the invention is characterized in that the swivel means is integral with a receiving head to connect to a longitudinal support inside the vertebral affixation system and with a pedicle screw.

Essentially the advantages of the invention are that the swivel means of the invention allows simpler design and lesser height than ball joints.

The invention and its further developments are elucidated below in relation to several illustrative embodiments shown in the partly schematic Figures.

Fig. 1 is a longitudinal section and a topview of a bone plate into which is integrated an swivel means of the invention,

Fig. 2 is a topview of a bone plate into which is integrated another embodiment of the swivel means of the invention,

Fig. 3 is a longitudinal section through two femur plates into which is integrated another embodiment of the swivel means of the invention fitted with a hip screw,

Fig. 4 shows an elevation, a sideview and a bottom view of vertebral affixation means into which is integrated another embodiment of the swivel means of the invention,

Fig. 5 is a perspective of a vertebral unit into which is integrated a further embodiment of the swivel means of the invention,

Fig. 6 is a section of another embodiment of a vertebral unit into which is integrated another embodiment of the swivel means of the invention.

Fig. 7 is an elevation of the vertebral unit of Fig. 6; and

Fig. 8 is a view of the vertebral unit of Fig. 6 with cambered vertebral end plates.

Fig. 1 shows illustrative embodiment of the swivel means10 of the invention mounted in a bone plate 3. The bone plate 3 is fitted with screw-holes 7 running from its upper surface 13 to its lower surface 14. The screw-holes 7 have a central axis 12 and will receive bone screws 1. By milling two semi-circular slots 6 concentric with the screw-holes 7 but of larger diameter out of the bone plate 3, the annular gimbal 4 is implemented with the two mutually opposite connecting arms 5 to the bone plate. In the embodiment shown in Fig. 1, the connecting arms 5 and the gimbal 4 are made integral with the bone plate 3 in the embodiment of Fig. 1 and form parts of same. A borehole 8 and a borehole 9 are resp. so configured from the upper surface 13 and the lower surface 14 of the bone plate 3 coaxially with the central axis 12 that the thickness "a" of the gimbal 4 and of the connecting arms 5 is less than the thickness "b" of the bone plate 3. The embodiment of the swivel means 10 of the embodiment shown in Fig. 1 in this case is merely a single gimbal subtended by the arms 5 and of which the axis of rotation 11 runs through the connecting arms 5 and transversely to the longitudinal direction of the bone plate 3. The screw head 2 of the bone screw 1 rests on the gimbal 4 and if the bone screw 1 must be screwed obliquely into the bone, then the swivel means 10 of the invention allows inserting the gimbal 4 – before tightening the screw – pivoting the said element 4 by means of a bar inserted into the borehole 7 into the desired direction relative to the connecting arms 5. The bone screw 1 then can be screwed in place at the predetermined angle.

The embodiment of the swivel means 10 of the invention shown in Fig. 2 differs from that of Fig. 1 only in that further connecting arms 15 offset by 90ø from the connecting arms 5 are mounted on a circular outer gimbal 16 to which the connecting arms 5 are mounted on its inside. The outer and also mutually opposite connecting arms 15 link the circular outer gimbal 16 to the bone plate 3 and allow pivoting the outer gimbal 16 about an axis 18 running parallel to the longitudinal direction of the bone plate 3. The connecting arms 5 are mounted inside the circular, outer gimbal 16 and link the outer gimbal 16 to the inner gimbal 4 and allow the inner gimbal 4 to pivot about the axis 11 running transversely to the plate's longitudinal direction. The 90° offset of the inner connecting arms 5 relative to the outer connecting arms 15 makes possible a double gimbal system 10 between the inner gimbal 4 and the bone plate 3. As shown in the embodiment of Fig. 1, the inner gimbal 4, the connecting arms 5; 15 and the outer

gimbal 16 are integral with the bone plate 3. In this embodiment as well the connecting arms 5; 15 might be in the form of pins supported in the bone plate 3, in the outer gimbal 16 and in the inner gimbal 4.

Fig. 3 shows another application of the bone plate 3 shown in Fig. 1 or Fig. 2 with integrated swivel means 10. A hip screw 19 passes obliquely through the bone plate 2 and rests in it by means of the swivel means 10 shown in Fig. 1 or Fig. 2. Exactly as is the case for the embodiment of the swivel means 10 of Fig. 1, the screw head 20 of the hip screw 19 rests on the inner gimbal 4. The hip screw 19 being oblique to the bone plate 3, the inner gimbal 4 will be pivoted into the desired direction before the hip screw 19 will be put in place. As shown in Fig. 1 or Fig. 2, the gimbals are implemented by connecting arms 5; 15. Because the connecting arms 5; 15 form firm linkages between the bone plate 3 and the inner gimbal 4 or between the bone plate 3, the outer gimbal 16 and the inner gimbal 4, a restoring force is created when pivoting the swivel means 10 away from the rest position. In order that the hip screw 19 be loaded only by axial forces, however the above mentioned restoring forces must be compensated. In the shown application, compensation is implemented in that two bone plates 3; 26 are superposed and the shank 21 of the hip screws 19 is made to pass each time through a swivel means 10 of the invention. The two bone plates 3; 26 can be affixed by further bone screws 24 to the bone 25. The direction of the hip screw 19 can be adjusted and fixed in place by mutually displacing the two bone plates 3; 26. The bone plates 3; 26 and thereby the direction of the hip screw 19 are fixed in place by tightening the bone screws 24. The shank 21 of the hip screw 19 is guided through the boreholes 22; 23 in the inner gimbals 4 of the invention's swivel means 10 of the two bone plates 3; 26, whereby, in spite of the restoring forces of the connecting arms 5; 15 shown in Fig. 1 and Fig. 2, no forces will arise transversely to the longitudinal axis 27 of the hip screw 19 when the bone plates 3; 26 are fixed in place.

Fig. 4 shows another application of the swivel means 10 of the invention. As shown by Fig. 2, the swivel means 10 consists of an inner gimbal 4, an outer gimbal 16 and connecting arms 5; 15. In the present application the swivel means 10 connects a pedicle screw 29 to a device 34 affixing the pedicle screw 29 to a longitudinal support 32 within a vertebral affixation system. The inner gimbal 4, the outer gimbal 16 and the inner connecting arms 5 between the inner gimbal 4 and the outer gimbal 16 as well

as the outer connecting arms 16 between the outer gimbal and the receiving head 31 for the longitudinal support 32 are integral with the receiving head 31. The pedicle screw 29 is made to pass through the borehole 28, corresponding to the screw head 30, in the inner gimbal 4 until the screw head 30 rests on the borehole 28. If the pedicle screw 29 is oblique to the longitudinal axis 35 of the receiving head 31, the angle of deviation will be absorbed by the articulations 10 of the invention. If a double gimbal system 10 is used as shown in Fig. 2, the pedicle screw 29 can be pivoted relative to the receiving head 31 about the axes 36; 37 subtended by the connecting arms 5; 15. If, as shown in Fig. 1, a single gimbal swivel means 10 is used, the pedicle screw 29 can be pivoted only about one axis 36 or 37 relative to the receiving head 31.

The application shown in Fig. 5 of an embodiment of the swivel means 10 of the invention comprises a vertebral unit 38 and two of the swivel means 10 of the invention of which the inner gimbals 4 serve as rest surfaces for vertebral parts adjoining the implanted vertebral unit 38. The vertebral unit 38 is approximately right parallelipipedic and comprises a top side 39, a bottom side 40 a front side 41 and a rear side 42 and also two lateral faces 43 and 44. The vertebral unit 38 comprises further a through-borehole 45 running from the front side 41 to the rear side 42 and a through-borehole 46 running between the lateral faces 43 and 44. The top and bottom sides 39 and 40 resp. of the vertebral unit 38 are curved in such a way that the inner gimbals 4 of the swivel means 10 mounted on the top side 39 and on the bottom side 40 constitute the uppermost and lowermost surfaces of the top side 39 and bottom side 40 resp. Thereby, in this special application, the swivel means 10 of the invention allow also using the vertebral unit 38 when the lower and upper rest surfaces are non-parallel in the spinal column. The swivel means 10 of the invention are integrated into the vertebral unit 38 at the top and bottom sides 39 and 40 resp., that is, the vertebral unit 38 and the swivel means 10 of the invention are integral. As shown in Fig. 2, the swivel means consists of an inner gimbal 4 pivotably connected to an outer gimbal 16 by two connecting arms 5 which are mutually opposite along an axis. The outer gimbal 16 in turn is pivotably connected by two outer connecting arms 15 mutually opposite along an axis through them and offset by 90ø from the inner connecting arms 5 to the vertebral unit 38. As a result, the inner gimbal 4 acting as a rest surface for the parts of the spinal column touching the vertebral unit 38 is able to pivot about two mutually

orthogonal axes located in the plane of the top side 39 or of the bottom side 40 of the vertebral unit 38. In the present embodiment variation, the vertebral unit 38 comprises one swivel means 10 of the invention on the top side 39 and one on the bottom side 40 and may be used as an inter-vertebral element or as a substitute vertebral unit.

Another embodiment of the vertebral unit 38 is shown in Figs. 6, 7 and 8. The swivel means 10 integrated into the end plates 61 of the vertebral unit consist of two nested gimbals 4; 16 pivotably connected by connecting arms 5; 15. When the swivel means 10 is un-pivoted, the gimbals 4; 16 are in a plane formed by the axes of rotation 11; 18 and running parallel to the rest surface of the end plates 61 of the vertebral unit. The outer annular gimbals 16 are rotationally connected in the outward direction by two pivotable connecting arms 15 to the vertebral-unit end plates 61 assuming the shape of oval rings. The outer annular gimbals 16 also are rotatably connected inward by connecting arms 5 to the inner gimbals 4. The inner gimbals 4 are mounted to the two ends 63, 64 of a bar 60 which is perpendicular both to the plane subtended by the axes of rotation 11; 18 and to the inner gimbal 4. The two vertebral-unit end plates 61 therefore are each connected to the bar 60 by a swivel means10 so as to be pivotable about a particular axis of rotation 11; 18.

CLAIMS

1. A device comprising an osteo-synthetic implant or implant element and at least one swivel means (10) connected to the implant or implant element,
characterized in that
a) at least one swivel means (10) is in the form of a single flat gimbal,
b) the at least one swivel means (10) comprises at least one planar or annular gimbal (4; 16) and two flat, bar-shaped connecting arms (5: 15) per gimbal which are mounted in one axis (11; 18; 36; 37) and at the outer periphery of the gimbal (4; 16) and which form the axes of rotation, and
c) one gimbal (4; 16) per swivel means (10) is rotatably connected by the connecting arms (5: 15) to the implant or implant element

2. Device as claimed in claim 1, characterized in that the inner gimbal (4) is fitted with a borehole (7; 22; 23; 28) running perpendicularly to the gimbal's plane of pivoting defined by the pivoting axes (11; 18; 36; 37).

3. Device as claimed in either of claims 1 and 2, characterized in that the implant or implant element on one hand and the swivel means (10) on the other hand are integral.

4. Device as claimed in one of claims 1 through 3, characterized in that the two flat, bar-shaped connecting arms (5; 15) are dimensioned in such a way that due to the plastic deformation of the two connecting arms (5; 15) an angularly fixed position of the gimbal (4; 16) is achieved relative to the implant or implant element.

5. Device as claimed in one of claims 1 through 4, characterized in that the swivel means (10) comprises two gimbals (4; 16) nesting in each other in one plane, the particular inner gimbal (4) being connected by two connecting arms (5) to the particular outer gimbal (16) so as to be pivotable about an axis (11; 37)and in that the particular outer gimbal (16) is connected by two connecting arms (15) to the implant or implant element so as to be pivotable about an axis (18; 36).

6. Device as claimed in claim 5, characterized in that the pivot axis (11; 37) runs between the mutually nested gimbals (4; 16) and in the plane they subtend.

7. Device as claimed in either of claims 5 and 6, characterized in that the pivot axis (11; 37) between the mutually nested gimbals (4; 16) is offset by 90ø relative to the pivot axis (18) between the outer gimbal (16) and the implant or implant element.

8. Device as claimed in one of claims 1 or 4 through 6, characterized in that the flat, bar-shaped connecting arms (5: 15) in the at least one gimbal (4: 16) and in the implant or implant element (3; 26; 31; 39) are rotatably supported shafts.

9. Device as claimed in one of claims 1 through 7, characterized in that the gimbals (4; 16) and the implants or implant elements are mutually separated by slots (6; 17) as far as the connecting arms (5; 15).

10. Device as claimed in claim 9, characterized in that the slots (6; 17)are arcuate segments.

11. Device as claimed in one of claims 1 through 10, characterized in that the implant to which is affixed the swivel means (10) is an approximately right parallelipipedic bone plate (3) of thickness "b".

12. Device as claimed in claim 11, characterized in that the at least one gimbal (4; 15) is of thickness "a" less than the thickness "b" of the bone plate (3).

13. Device as claimed in either of claims 11 and 12, characterized in that the flat, bar-shaped connecting arms (5; 15) are of thickness "a" less than the thickness "b" of the bone plate (3).

14. Device as claimed in one of claims 1 through 10, characterized in that the swivel means (10) is integrated into a receiving head (31) to connect a pedicle screw (29) to a longitudinal support (32) within a vertebral affixation system.

15. Device as claimed in claim 14, characterized in that the swivel means (10) forms an integral unit with at least one gimbal (4), with the receiving head (31) for connection to the longitudinal support (32) and with the pedicle screw (29).

16. Device as claimed in one of claims 1 through 10, characterized in that the implant is in the form of an inter-vertebral unit (38) or a vertebral replacement unit.

17. Device as claimed in claim 16, characterized in that one swivel means (10) each is integrated in an inter-vertebral unit (38) in a surface that can be matched to the adjacent vertebras both at the top side (39) and at the bottom side (40).

18. Device as claimed in claim 16, characterized in that two swivel means (10) are affixed by their inner gimbals (4) perpendicularly to the pivot axes (11; 18) to the ends (63; 64) of a bar (60) of length "c" and in that a gimbal (4; 16) is connected at each swivel means (10) to a vertebral end-plate (61).

19. Device as claimed in one of claims 1 through 14, characterized in that the swivel means (10) is designed to receive a bone affixation means.

20. Device as claimed in claim 19, characterized in that the device acting as bone affixation means additionally comprises a bone screw (1; 19) passing through the borehole (7) in the gimbal (4) and of which the screw head (2) rests on the gimbal (4) and in that this bone screw (1; 19) is received by means of the swivel means (10) in the bone plate (3) so as to be rotatable about at least one axis (11; 18).

21. Device as claimed in claim 19, characterized in that it comprises an additional pedicle screw (29) as the bone affixation means, this screw (29) passing through the borehole (28) in the gimbal (4) and its head (30) resting on the gimbal (4), and in that this pedicle screw (29) is received by means of the swivel means (10) in the receiving head (31) of the vertebral affixation system (50) so as to be rotatable about at least one axis (36; 37).

22. Device as claimed in either of claims 20 and 21, characterized in that the borehole (28) in the gimbal (4) is conical and in that the bone affixation means, ie the bone

screw (1; 19) or the pedicle screw (29) comprises a screw head (2; 20; 30) fitted with a corresponding cone and in that thereby a fixed angular connection can be established between the implant or implant element and the bone affixation means.

23. Device as claimed in either of claims 20 and 21, characterized in that the borehole (28) in the gimbal (4) is fitted with an inside thread and in that the bone affixation means or the bone screw (1; 19) or the pedicle screw (29) is snugly provided at the screw head (2; 20; 30) or at a portion of the shank with a corresponding outer thread and in that thereby an angularly fixed connection can be established between the implant or implant element and the bone affixation means.

24. Device as claimed in either of claims 20 and 21, characterized in that the borehole (28) in the gimbal (4) is fitted with an inside conical thread and in that the bone affixation means or the bone screw (1; 19) or the pedicle screw (29) is snugly fitted at the screw head (2; 20; 30) or at a shank segment with a corresponding outside thread and in that thereby an angularly fixed connection can be established between the implant or implant element and the bone affixation means.

25. Device as claimed in either of claims 20 and 21, characterized in that the bone affixation means or the bone screw (1; 19) or the pedicle screw (29) is fitted with an expansible head (2; 20; 30) and in that, by means of a tightening screw, the parts of this expansible head are press-fitted against the wall of the borehole (28) and that thereby an angularly fixed connection can be established between the implant or implant element and the bone affixation means.

26. Device as claimed in one of claims 1 through 25, characterized in that the swivel means (10) is a planar double-gimbal system.

ABSTRACT

A device comprising an osteosynthetic implant or implant element and at least one swivel means 10 connected to the implant or implant element. Each swivel means 10 comprises at least one planar or annular gimbal 4, 16 and two bar-shaped connecting arms 5, 15 per gimbal 4, 16, said arms being configured along one axis 11, 18, 36, 37 and at the outer periphery of the gimbal 4, 16 and constituting the pivot axes. One gimbal 4, 16 is rotatably connected by the connecting arms 5, 15 to the implant or implant element. Depending on the design of the swivel means 10, it is used to receive a bone affixation means 1, 19.

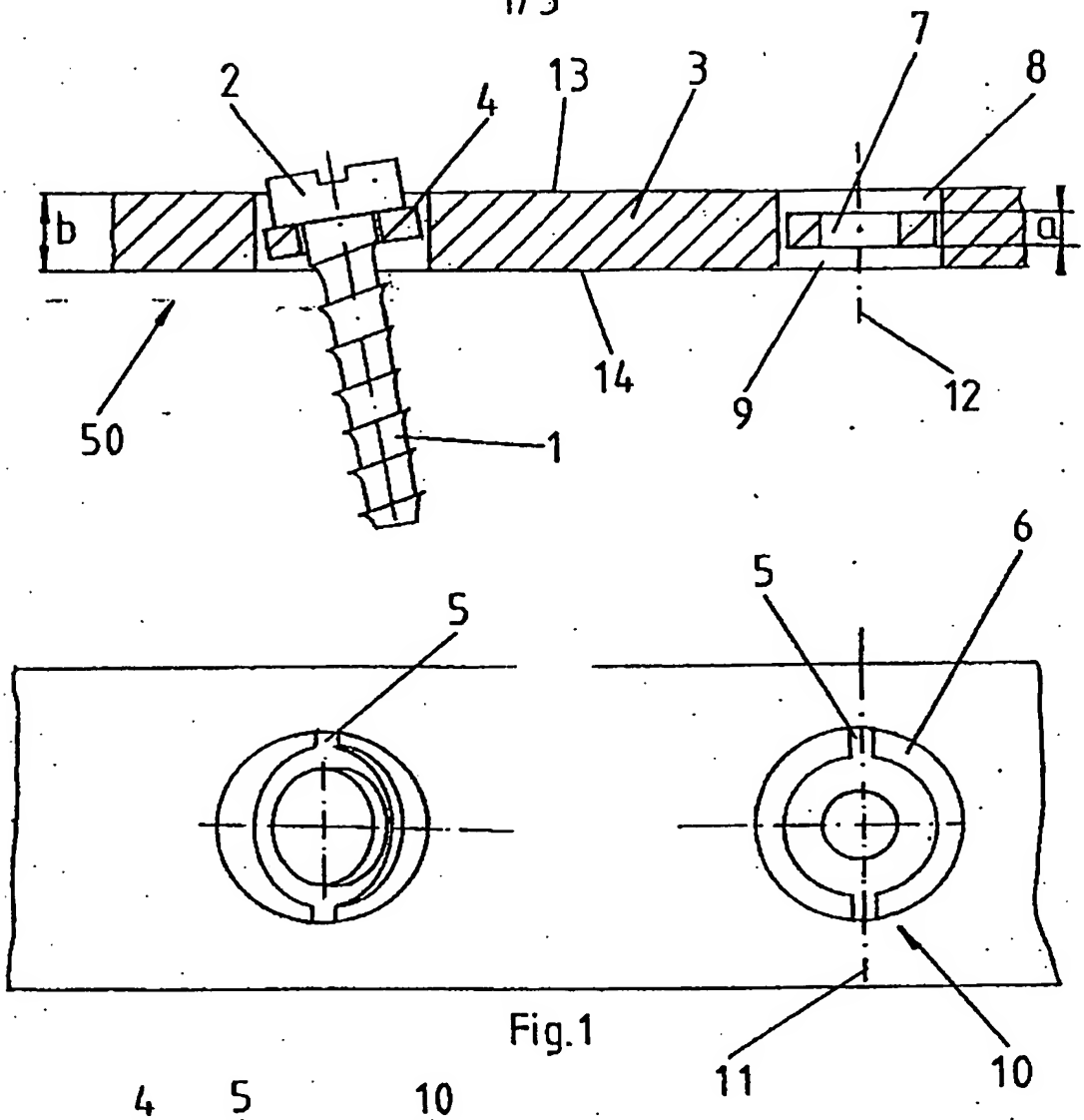



Fig.1

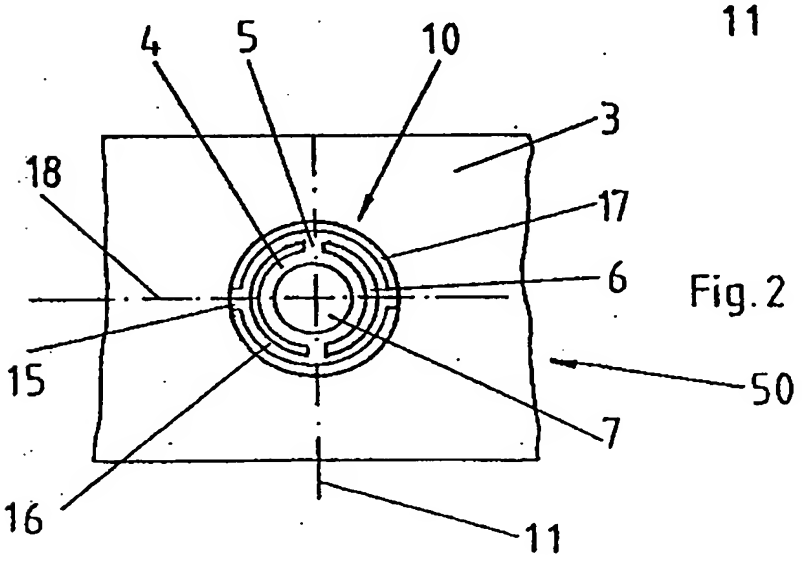



Fig. 2

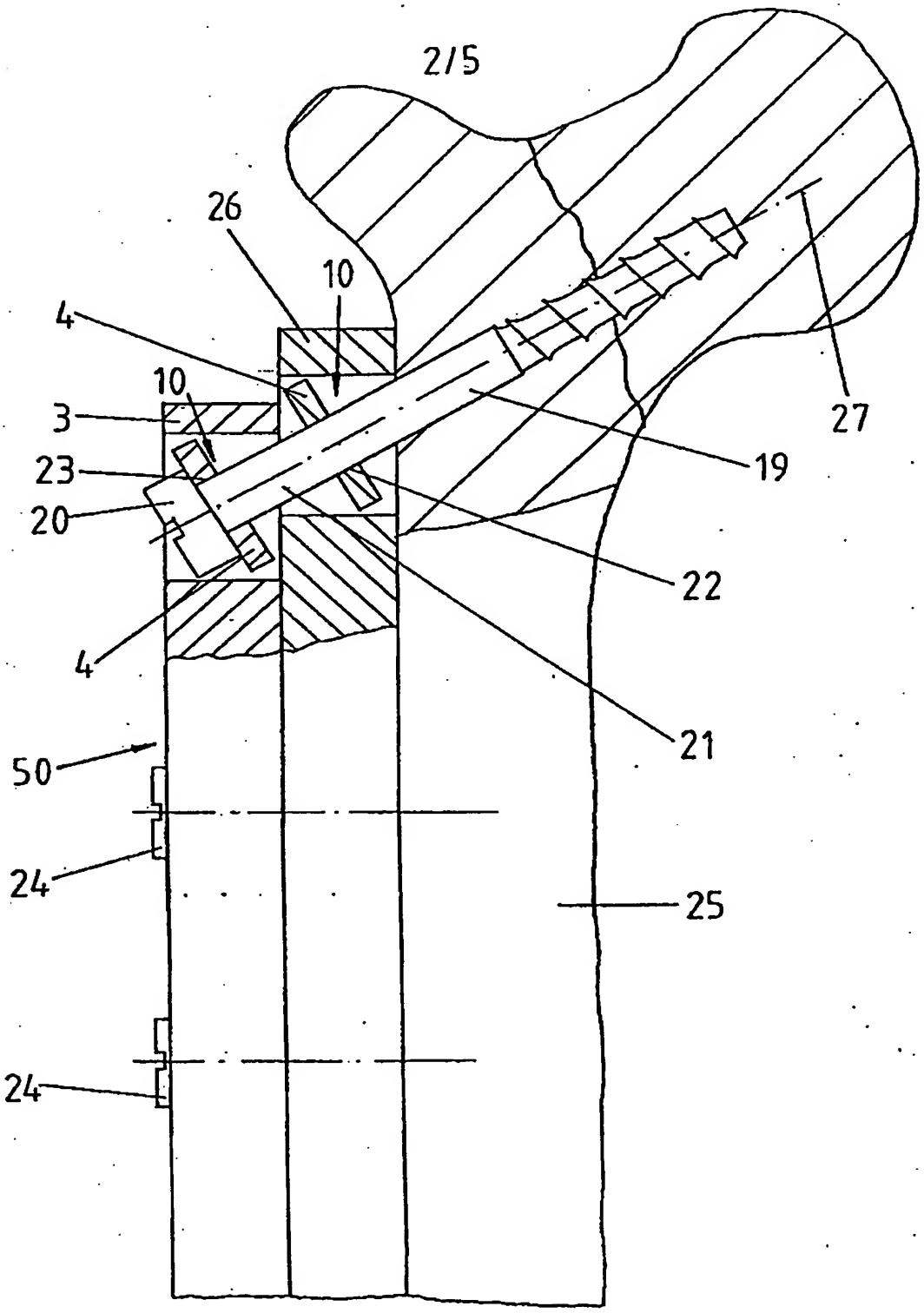
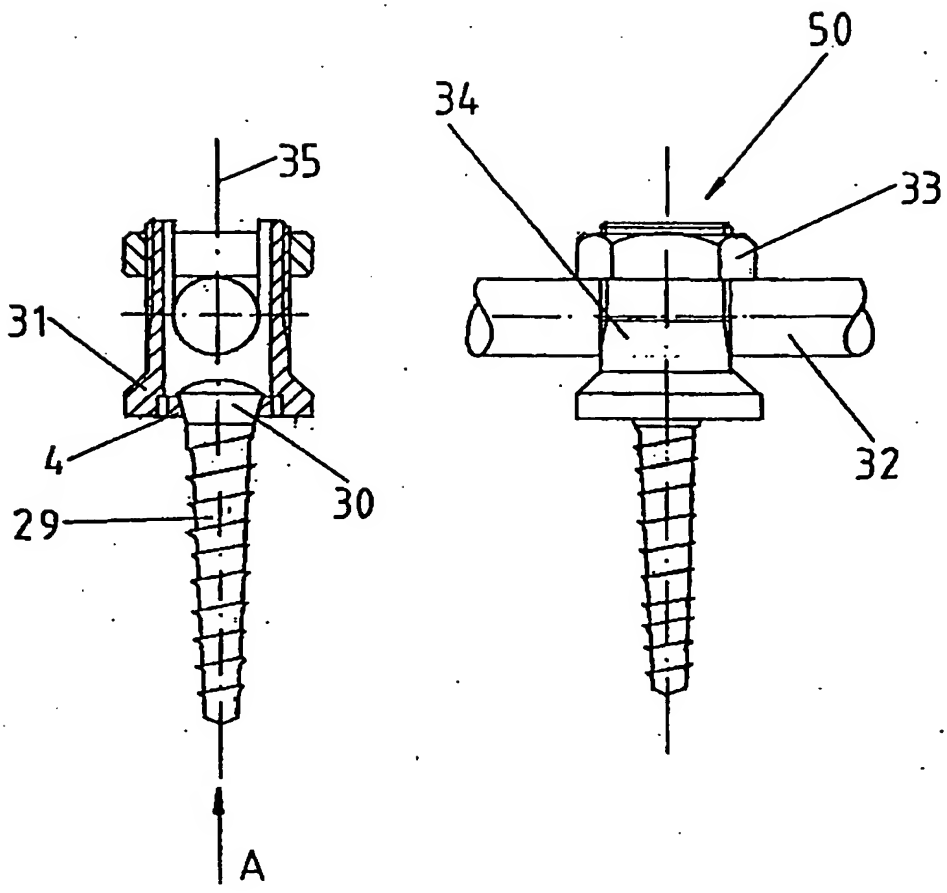



Fig. 3

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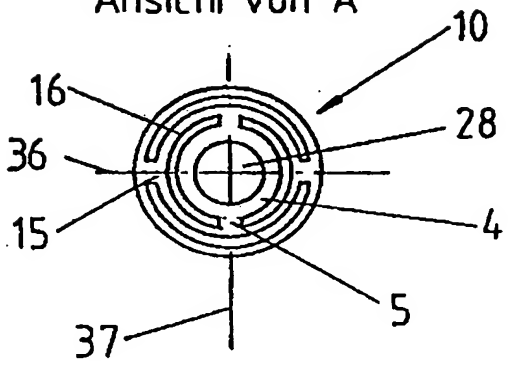



Fig.4

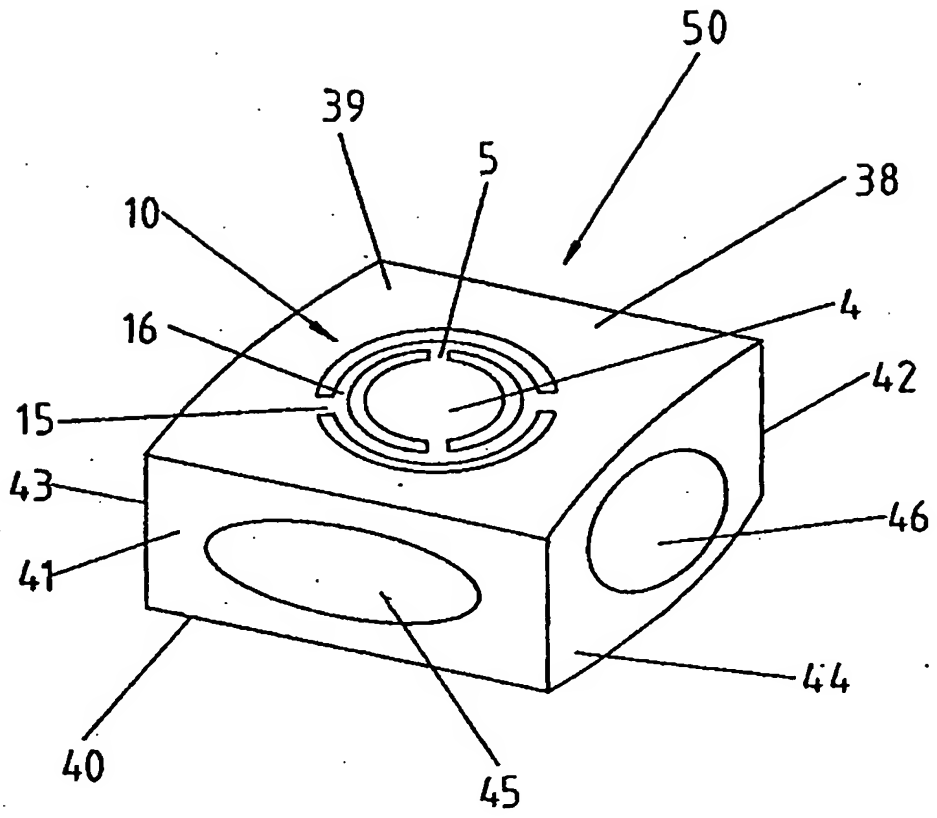



Fig.5

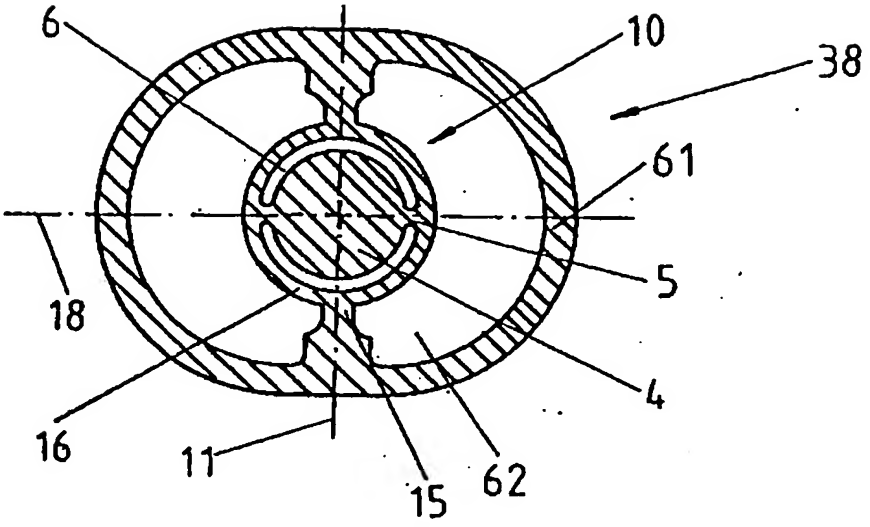



Fig.6

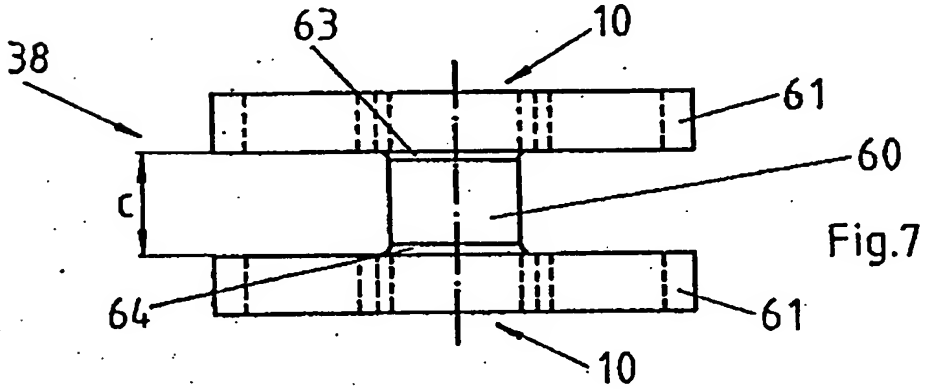



Fig.7

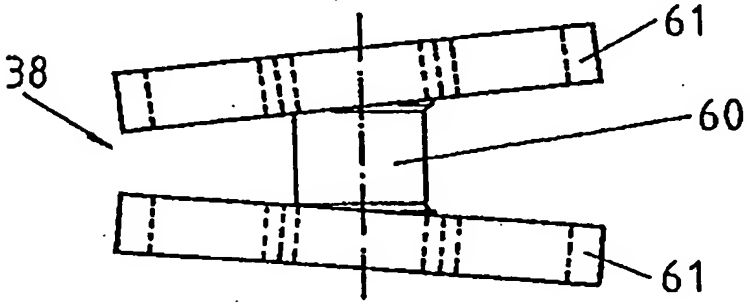
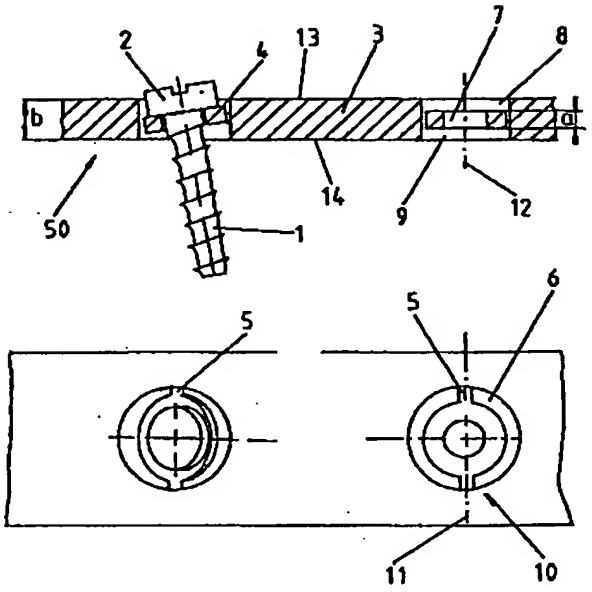



Fig. 8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